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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,855	10/13/2000	Chaitan Khosla	286002021100	6952

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EXAMINER

KERR, KATHLEEN M

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 01/24/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/687,855

Applicant(s)

KHOSLA ET AL.

Examiner

Kathleen M Kerr

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Application Status

1. Claims 1-43 are pending in the instant application.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1-9, 24-29, and 42-43, drawn to host cells modified to produce polyketides, classified in class 435, subclass 252.3.
 - II. Claims 10, 13-23, and 30-32, drawn to methods of making polyketides, classified in class 435, subclass 76.
 - III. Claims 11-12, drawn to methods of assessing genetic modifications in host cells, classified in class 435, subclass 4.
 - IV. Claims 33-39, drawn to reaction mixtures for producing polyketides, classified in class 435, subclass 183.
 - V. Claims 40-41, drawn to methods of making polyketides using reaction mixtures, classified in class 435, subclass 76.
3. The inventions are distinct, each from the other because of the following reasons:

Group I is related to Groups II and III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

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product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the host cell products can be used for a materially different process of using that product, such as in the recombinant production of the polyketide synthase enzymes. Thus, Group I is patentably distinct from Groups II and III. Moreover, a search burden is clear from the distinct class/subclass groupings.

Group I is related to Group IV because the host cells of Group I can make the enzymes that make up the reaction mixtures of Group IV. However, these products are wholly different products having wholly different functions. Moreover, the reaction mixture products can be obtained independent from the host cells, for example by purification from natural sources. Thus, Groups I and IV are patentably distinct. Moreover, a search burden is clear from the distinct class/subclass groupings.

Groups I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case, the products of Group I may contain the reaction mixtures useful in the methods of Group V; however, the products are not disclosed as being used in the methods themselves. Thus, Groups I and V are patentably distinct. Moreover, a search burden is clear from the distinct class/subclass groupings.

The methods of Groups II and III are distinct from each other based on their distinct methods steps, reactants and products. The distinct methods are useful for wholly different purposes. Thus, Group II is patentably distinct from Group III. Moreover, a search burden is clear from the distinct class/subclass groupings.

The methods of Groups II and III are distinct from the products of Group IV. The Group IV products are not used in the claimed methods as either products or reactants. While the Group IV products may be found in the host cells used in the methods of Groups II and III, the Group IV products are wholly distinct from the host cells for the reasons cited above. Thus, Groups II and III are patentably distinct from Group IV. Moreover, a search burden is clear from the distinct class/subclass groupings.

The methods of Groups II and V are distinct from each other based on their distinct methods steps, reactants and products. The distinct methods are useful for wholly different purposes. Thus, Group II is patentably distinct from Group V. Moreover, a search burden is clear from the distinct class/subclass groupings.

The methods of Groups III and V are distinct from each other based on their distinct methods steps, reactants and products. The distinct methods are useful for wholly different purposes. Thus, Group III is patentably distinct from Group V. Moreover, a search burden is clear from the distinct class/subclass groupings.

Group IV is related to Group V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the reaction mixture products can be used for a materially different process of using that product, such as in the production of antibodies. Thus, Group IV is patentably distinct from Group V. Moreover, a search burden is clear from the distinct class/subclass groupings.

Notice of Possible Rejoinder

4. The Examiner notes that if product claims in Groups I or IV are found directed to allowable products, then process claims in Groups II and III (related to Group I) or Group V (related to Group IV), which are directed to processes of using the patentable products, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re Ochiai*, and *In re Brouwer*). Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Election

5. A telephone call was made to Kate Murashige on January 17, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

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Conclusion

6. A complete response to the instant Office action must include an election of invention to be examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


PONNATHAPUACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

KMK
January 17, 2002